

### **REMARKS**

Upon entry of the amendment claims 44-56 will be under examination. Claims 1-43 have been withdrawn from consideration. Claims 57 and 58 have been cancelled. No new matter has been added.

#### **Rejections under 35 USC §112 second paragraph**

Claims 57-58 are rejected as indefinite. Applicants have cancelled the claims.

#### **Rejections under 35 USC §102(b)/103(a)**

Claims 44-56 are rejected as being anticipated by, or in the alternative, as obvious over, Conteas, et al. ("Conteas"). The rejection is traversed for the reasons to follow.

Claim 44, from which claims 45-51 depend, requires that the gastrin/CCK receptor ligand and EGF receptor ligand in the kit are suitable for inclusion in a pharmaceutical composition for administration to a human patient. Similarly, claim 52, from which claims 53-56 depend, specifies that the recited ligands are suitable for preparing a pharmaceutical composition suitable for administration to a human patient.

The Examiner asserts that it would be fair to conclude that the gastrin and EGF in Conteas et al were in vials for shipment and were in close proximity to one another at some point in time, and a refrigerator or a cabinet could be considered a "container" and therefore constitutes a kit. However, a person skilled in the art would not reasonably conclude that a refrigerator or a cabinet constitute a kit for administration of sterile components to a patient. In fact, the Examiner in her comments at page 5, refers to the "container" as a box. Conteas et al lacks any disclosure of packaged material comprising sterile gastrin and sterile EGF components. . The gastrin and EGF utilized by Conteas et al in the in vitro experiments described in the publication were obtained from different companies in different states on opposite coasts of the US. The gastrin was obtained from Peninsula Laboratories in California and the EGF was obtained from Collaborative Research Waltham, Massachusetts. Therefore, there is no teaching or suggestion in Conteas et al of a kit comprising a container such as a box with sterile gastrin and sterile EGF for administration to a patient .

Further, contrary to the Examiner's assertion, Conteas et al do not teach the "administration" of gastrin and EGF either alone or in combination or for therapeutic applications, and a kit for therapeutic applications would not reasonably flow from the teachings of the publication. Conteas et al incubated IEC-6 cells, a small intestinal crypt cell line, containing normal non-tumor cells, with GI hormones and peptides, to investigate the role of these hormones and peptides in the regulation of GI mucosal cell proliferation in normal cells. Conteas et al do not teach or suggest any in vivo applications, in particular therapeutic applications for gastrin and/or EGF, or any kits with therapeutically effective amounts of gastrin and/or EGF suitable for administration to humans. Conteas et al clearly do not disclose forms for administration of the compounds that are suitable for human patients such as those contemplated in the present application (see paragraph 0037 in the published application) or mentioned by the Examiner (i.e. syringes or i.v. bags).

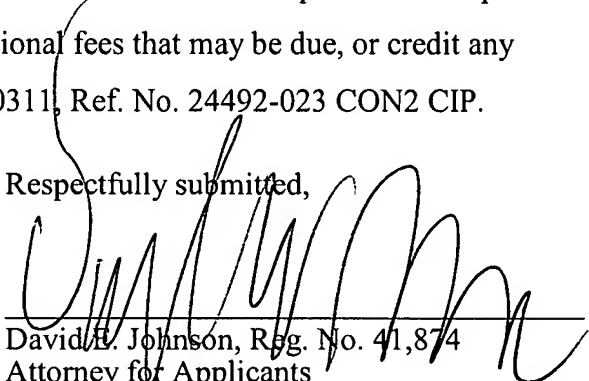
Applicants request reconsideration and withdrawal of the rejection.

Obviousness-type Double Patenting

Claim 52 is rejected for double-patenting over claim 7 of US Patent No. 6,288,301. The rejection is traversed to the extent it is applied to the claims as amended. Applicants will submit a terminal disclaimer upon indication of allowable subject matter in this application.

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. A petition for three-month extension of time accompanies this response. The Commissioner is authorized to charge any additional fees that may be due, or credit any overpayments of same, to Deposit Account No. 50-0311, Ref. No. 24492-023 CON2 CIP.

Respectfully submitted,

  
David E. Johnson, Reg. No. 41,874  
Attorney for Applicants  
c/o MINTZ LEVIN  
Tel: (617) 542-6000  
Fax: (617) 542-2241  
**Customer Number 30623**

Dated: April 13, 2007